Patient Experience of Pregnancy-Related Venous Thrombosis: A Phenomenological Study

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Shortened Title: Patient Experience of Pregnancy-Related Venous Thrombosis

Abstract

This study used a descriptive phenomenological approach to explore the lived experience of women diagnosed with VTE in pregnancy and the perinatal period. The study setting was a London, university affiliated hospital. The sample consisted of nine women with deep vein thrombosis or pulmonary embolism in pregnancy or up to six weeks post-partum, diagnosed in the last two years. Semi-structured interviews were undertaken using an interview guide. Interviews were transcribed and analysed using phenomenological descriptive analysis. Clustered invariant constituents that represented the lived experience of subjects emerged.

The study revealed that the experience of pregnancy-related venous thrombosis is an overwhelmingly negative one with the journey through diagnosis and treatment being fraught with challenges, uncertainty and anxiety. Four main themes that contributed to the women's lived experience were identified; 1. Challenges in establishing a diagnosis 2. Dealing with diagnosis 3. Coping with treatment 4. Fears for the future.

This is the first study to explore the experience of pregnancy-related venous thrombosis and offers valuable insight into the phenomenon. There is opportunity for clinicians to enhance the experience of pregnancy-related venous thromboembolism (PRVTE) by improving communication and information given to patients, clarifying diagnostic and treatment pathways and improving awareness of the condition.

Keywords

Pregnancy-related thrombosis, venous thromboembolism, pulmonary embolism, patient experience, anxiety

Introduction

Pregnancy and the puerperium represent clear provoking risk factors for venous thromboembolism (VTE) since the physiological changes of pregnancy induce a pro-thrombotic state [1] The incidence of VTE in pregnancy and the puerperium ranges from 0.5-2.2 episodes/1000 deliveries [2-6] and is the leading cause of direct maternal death in the UK [7]. Patient experience is an established component of quality care and understanding the patient experience is essential if care is to be improved [8]. Four studies have examined patient experience of VTE in various non-pregnant populations; two in cancer associated thrombosis patients [9-10], one in percutaneous intravascular catheter associated thrombosis [11] and one in acute VTE [12]. These studies consistently found VTE to be a negative experience which provokes strong emotional reactions. For some, the experience is life changing with fear of VTE recurrence an everlasting consequence [11,12]. Additionally, treatment has been found to be challenging, particularly for younger adults and those requiring injections rather than oral medication. Those with pre-existing conditions such as cancer and infection viewed VTE as an additional burden [9, 10, 11, 12]. Participants in all studies felt let down by Health Care Professionals (HCPs) who did not meet their needs for swift diagnosis, information about VTE or emotional support.

Women with pregnancy-related VTE (PRVTE) face a unique set of challenges compared to the non-pregnant population; PRVTE is more difficult to diagnose due to common manifestations of pregnancy mimicking VTE [1], necessity of treatment via injections rather than tablets [13], management of anticoagulation around delivery to minimise the risk of thrombosis and haemorrhage [14] and low molecular weight heparin (LMWH) being a requirement throughout future pregnancies [15]. The impact PRVTE has on women is unknown but pregravid morbidity is shown to negatively affect the wellbeing of the infant with potential to negatively affect bonding and increase risk of maternal anxiety and depression [16, 17].

In this study, we explored the lived experience of women diagnosed with PRVTE including the impact of diagnosis and treatment, the influence of PRVTE on the birth experience and of having a new baby and the effects on partners and family members.

Methods

This study adopted a descriptive phenomenological approach to explore the experience of PRVTE through audio-recorded, face-to-face, semi-structured interviews. A purposive sampling technique was employed. Patients diagnosed with VTE in pregnancy or up to six weeks postpartum within the previous two years at a London teaching hospital (n=45) were invited to participate in the study via letter to their home address or provided at outpatient appointment. Participants were included in the study if they received a VTE diagnosis within the last two years, were over the age of 16 at diagnosis, had pregnancy resulting in live birth, were able to speak, read and write English, provide informed consent and were previously unknown to the researcher. Participants had the choice of being interviewed at home or in hospital. Patient and public involvement was sought via Thrombosis UK, a charity which raises awareness about VTE, for the design of the participant information sheet and interview guide to ensure both were comprehensive and relevant. The interview guide was pilot tested and refined by the primary researcher. All interviews were undertaken by the primary researcher, a female MSc student and Nurse Consultant in Thrombosis and Coagulation. Field notes were taken after each interview and a reflexive diary was kept ensuring non-verbal communication was captured. All nine participants were interviewed once between May and July 2018. Interview duration ranged from 16 to 50 minutes. Participants were aged between 24 and 40 years (mean age 33 years); four had been diagnosed with pulmonary embolism, and five with deep vein thrombosis (three distal, two proximal). Six participants had been diagnosed with VTE in pregnancy and three post-partum. Time from VTE ranged from 2-24 months (median 13). Seven participants were White British and two were African Caribbean (see Table 1). Two women had previously experienced VTE, one of whom received thromboprophylaxis in pregnancy.

Interview audio recordings were transcribed verbatim and analysed using Giorgi's [18] five step method of descriptive analysis. This included: (1) bracketing of presuppositions and experiences to ensure data was viewed in its own context (2) review of audiotapes and transcripts until a sense of the whole experience was achieved (3) highlighting and numbering 'meaning units' in the text to divide data into manageable portions (4) transforming meaning units into statements summarising their content and (5) clustering similar statements until themes emerged. This process was undertaken manually without the use of data analysis software.

The first two transcripts were analysed by two members of the team (EG and VT) independently and then collaboratively checked for consistency. The study was approved by the London Bridge Research Ethics Committee in April 2018 (REC No:18/LO/0284) and King's College Hospital NHS Foundation Trust Research and Innovation department. All participants provided written informed consent prior to interview.

Results

Eleven participants indicated willingness to participate in the study and nine interviews were conducted (two participants could not be contacted). Common aspects of the lived experience emerged from data analysis and were clustered to create four main themes: 1. Challenges in establishing a diagnosis, 2. Dealing with diagnosis, 3. Coping with treatment, and 4. Fears for the future.

1. Challenges in establishing a diagnosis

All of the women experienced some form of difficulty in establishing a diagnosis of VTE. On initial presentation, six participants were told by HCPs that symptoms such as shortness of breath, leg pain and swelling and syncope were secondary to pregnancy. When eventually diagnosed with VTE, some women felt frustrated and angry about being dismissed and questioned whether their VTE was more severe due to the delay in diagnosis. Participant six developed pain in her leg during

pregnancy that was dismissed multiple times by doctors and midwives until three weeks after the birth of her baby via caesarean section:

"*I was constantly back up there, each time I kept saying about my leg, in that first week and each time they looked at it and said no, it's not a DVT, it's not red, it's not swollen and I was sure that it was."*(P6)

Five women felt they received insufficient information from HCPs during the diagnostic process generating worry and frustration. Lack of prior knowledge of VTE meant that some women were unaware they were being investigated for this purpose, as one woman recounted:

"I had a VQ scan and it wasn't until I came back to A and E, I remember her [the doctor] coming over to me, she had the clexane needle in her hand and she went, we've diagnosed that you've got a blood clot on your lung and you need to have treatment for it. She said I've got an injection for you now. And that was the first point, nowhere along the line had anyone said to me that was what they were suspecting at all." (P3)

Another cause of anxiety for two women was the potential maternal and foetal risks associated with diagnostic scans for PE as they found it difficult to get clear information about the risks involved.

"*I wanted somebody to explain to me what the test was and what precisely they were putting into my system and what impact or risk that might have on my baby. All they kept saying was, if you don't have it done the impact on you is going to be worse. I get that, but equally I did, I sort of refused to have it, until someone could explain to me what I was signing up for*." (P4)

2. Dealing with diagnosis

The most common reaction to diagnosis of VTE by the women was shock, exacerbated by limited VTE awareness and perception of themselves as healthy. In addition, women diagnosed with VTE in the puerperium perceived VTE as an additional encumbrance to birth or baby complications:

"*It was a shock really cos we'd had quite a bit of stress since she'd been born so….., it was quite stressful dealing with a new born baby who'd had minor surgery at 2 days old and I was on iron tablets because of the blood loss so I was really tired and weak*" (P2)

Experience of VTE was inextricably linked to the birth experience for four women. Some women became emotional when recounting their traumatic birth experiences which inevitably impacted on their ability to cope with VTE at that time.

Shock was accompanied by confusion and misunderstanding for some as they grappled with understanding what VTE meant for them and their pregnancy. This was often exacerbated by a lack of written and verbal information available from HCPs. As well as the women themselves, VTE had a significant impact on partners and the women's mothers who found the experience a stressful and worrying time. One woman who developed a DVT in pregnancy described the fears her partner had about how VTE might affect their pregnancy:

"*There were concerns and worries at the time about having a blood clot, my boyfriend was extra worried, and he was like, should we continue with the pregnancy, so that was extra pressure…..I think it was difficult to just try and get information from people [HCPs] as to how is it going to impact on the pregnancy."* (P8)

3. Coping with treatment

All women received LMWH injections at least some of the time and all experienced them to be painful and unpleasant. There was a general sense of having no option but to cope. Daily injections were particularly arduous for three participants and impacted significantly on their lives, as one participant whose DVT was diagnosed after caesarean section described:

"*I'd get that injection out of the way and be like oooh, …I can relax now, by the time I get up next morning I was anticipating it the whole day…….I absolutely hated it, and it just hurt as well and I felt*

like I was being inflicted with so much pain, constantly. Especially in your stomach that hurts anyway, and I did try my leg but that was horrendous, that was even worse." (P6)

Six participants administered the injections into their abdomen which some found difficult during pregnancy:

"*Yes, and I was worrying that it's going to hurt him [baby], but I was reassured that it wouldn't. Yes, it was very painful."* (P9)

Adhering to treatment became more difficult after the birth for five women due to the demands of caring for a newborn and the physical and emotional impact of the birth as one woman recounted:

"..that was a pain. Yes, that was a real chore…you just forget because you are so busy, you are tired, you are exhausted, and you forget." (P4)

A variety of different concerns surrounded management of anticoagulation around the birth for the women. Some feared the risks of thrombosis and haemorrhage in the peripartum phase with one woman fearing the worst*:*

"I thought I was going to die. I thought I was going to die giving birth. That was probably the worst feeling because I thought, he's not going to have a mum" (P9).

For others, inconsistent instructions from Doctors about the LMWH and birth plan was a major stressor. Those told to stop LMWH when in established labour feared not knowing when labour was 'established', whilst one woman was concerned about rapid labour and delivery occurring soon after a LMWH injection. Women also worried that epidural would not be permitted within 24 hours of LMWH, limiting their analgesia options also meaning that in the event of emergency caesarean section, general anaesthetic would be required which would preclude partners from being present during the birth.

4. Fears for the future

Five women were concerned about the prospect of VTE recurrence, with some suggesting that a repeat scan at the end of treatment would have given them closure on the episode:

"I was really surprised they didn't scan my leg again because kind of, I thought, surely, you'd want to check that the clot's definitely gone, I guess maybe that's a kind of lingering kind of worry that I've never had confirmation that it went, what if it's still there?" (P2)

Three women presented to an HCP with VTE symptoms after cessation of treatment and although VTE was ruled out in all cases, concern appeared to be heightened due to the low specificity of VTE symptoms such as leg and chest pain. Fear of recurrence played on the minds of these participants, with one stating that anxiety about leg symptoms could change her mood instantly, and another resorting to taking LMWH injections when going on long car journeys to lessen the concern. Participants experienced anxiety in trying to decide if symptoms were real and required medical attention. One woman describes a coping mechanism she developed for this:

"Sometimes I just would think "Oh.. Is it just in my head?", because it's not a constant feeling. That's when I would check and sort of like go to bed at night and just say "Okay, if it's there in the morning then, we need to look at that." (P5)

Finally, some women expressed concern about the impact of VTE on future pregnancies due to the prospect of requiring LMWH throughout the entire pregnancy, as well as health concerns for themselves and their babies.

"The worst bit out of all of it is the future pregnancy risk, the pain, the stress wasn't great but that's not the lasting thought for me, it's more the future." (P2)

Three participants said their increased risk of VTE would be a significant factor for consideration when deciding whether to have another baby, as described by one participant:

"My husband would really like us to have another baby. I had IVF so the whole thing actually just now becomes, I don't know, it's another thing for me to think no I don't want to do it again" (P4)

Discussion

This study examined the patient experience of PRVTE and supports findings from previous studies in non-pregnant populations [9, 10, 11, 12] with the addition of some aspects of the experience unique to women in pregnancy or the puerperium.

All women faced difficulties and delays during the diagnostic phase, with some having symptoms dismissed by HCPs multiple times. VTE is difficult to diagnose, particularly in pregnancy [19, 20] with typical VTE symptoms also being common gestational sequelae. Additionally, established methods for predicting clinical risk of DVT are not validated in pregnancy and d-dimer is redundant due to its natural elevation in pregnancy [20]. Consequently only 10% of pregnant women with symptoms suggestive of thrombosis have confirmed VTE, compared to 25% in the non-pregnant population [21]. Despite this, in their study of acute VTE in a non-pregnant population Hunter et al [12], also found that participants were repeatedly dismissed by HCPs suggesting this is not an issue unique to PRVTE.

Delays in diagnosis were compounded by lack of VTE awareness amongst the women. Similarly, a large study examining global public awareness of VTE found pregnancy to be one of the least recognised risk factors [22]. In addition, two studies looking at patient experience of VTE in non-pregnant populations [10,11] highlighted limited prior knowledge of VTE amongst participants. RCOG guidance [13] only recommends providing information about VTE to women if they are assessed as high risk but this study suggests that provision of information about VTE would be warranted and beneficial to all women in early pregnancy.

Most women in this study felt shocked when diagnosed with VTE, sometimes compounded by perception of themselves as healthy, a reaction also found by Hunter et al [12] in non-pregnant VTE sufferers. For women in this study, VTE diagnosis represented transformation from normal to high-risk pregnancy. Murphy and Robbins [23] claim that previously healthy women who develop

complications in pregnancy experience a higher level of 'crisis', further amplified if the condition is life threatening to mother or foetus, as is the case with VTE.

Despite all having good physical health outcomes, the women in this study found PRVTE an overwhelmingly negative experience, fraught with stress and anxiety. This supports the notion proposed by Goldhaber [24] that HCPs have focused heavily on the physical effects of VTE and largely ignored the emotional burden. This is particularly relevant for women with PRVTE as a clear correlation exists between maternal stress and adverse pregnancy outcomes [25]. The triggers for stress and anxiety amongst the women varied and previous experiences such as invitro fertilisation, previous VTE and previous morbidity impacted on the individual experience.

While most women in this study adapted to self-administering LMWH, some found it challenging, a finding consistent with a study that explored women's views on, and adherence to LMWH in pregnancy and the puerperium [26]. They found that although participants disliked injections, most accepted them as necessary in protecting their unborn baby.

Consistent with this study, Martens & Emed [27] and Patel et al [26] also found that women taking LMWH in pregnancy worried about options for pain relief and the health risks associated with stopping treatment for the birth. HCPs have a role to play in reducing this anxiety by ensuring women have clear information about the plan for anticoagulation around the birth.

Difficulties with treatment extended to the post-partum period as some participants found that having a new baby impaired their ability to adhere to treatment, a finding supported by Patel et al [26] who discovered that adherence to treatment decreased for some women in the puerperium, with the main reasons cited as disruption to routine (unintentional non-adherence) and the feeling that treatment was less important in the puerperium since it no longer had a role in protecting the health of their baby (intentional non-adherence). This again suggests the need for better information provision since the post-partum period is associated with the highest risk of VTE [1].

This study revealed that the partners and mothers of women with VTE also experienced anxiety and worry. Two participants felt that their mother's reactions adversely affected them but otherwise VTE did not appear to impact on these relationships.

The focus of worry and anxiety was slightly different for those diagnosed in the post-partum period to those diagnosed in pregnancy. Diagnoses in the post-partum period were associated with anxiety around the practicalities of adhering to treatment and attending hospital appointments whilst the pregnancy diagnoses were associated with more anxiety around the shock of being diagnosed with a VTE and the discomfort of treatment.

All patients receive information about VTE at their first appointment with a midwife at the hospital in which the study took place. As a result of the study a specific pregnancy-related thrombosis leaflet is in development for those suspected of or diagnosed with VTE. The study findings have been disseminated to relevant clinicians to raise awareness of the issues faced by women. Additionally, an audit of anticoagulation management around delivery is planned to ensure this care is optimised.

Strengths and Limitations

This is the first study to examine the patient experience of PRVTE providing novel insight into the psychological aspects of the event, at a time when clinicians are becoming increasingly aware of the importance of treating the mind and body in unison.

This was a single centre study with a small sample size, which although appropriate for phenomenological research, may not reflect the experiences of all women with PRVTE. Only three participants had post-partum VTE, so experience of having VTE diagnosed in the puerperium may not have been fully captured. All participants conveyed some negative aspects of the experience which may have motivated their participation in the study and may not reflect the experiences of non-respondents. Furthermore, the study recruited patients from a London teaching hospital with a

specialist multi-disciplinary thrombosis team which may not reflect the experience of less specialised services. Additionally, the study took place in a country with universal state funded health care, in countries without this provision, the cost of treatment may prove an additional source of anxiety. Despite the study taking place in a region of ethnic diversity, black, Asian and minority ethnic populations were underrepresented. The study was undertaken by a previously research naive MSc student which may have impacted on the interview technique and analysis, although undertaking pilot work and working closely with experienced researchers in academic and clinical capacities helped minimise this as a limitation. Every attempt was made by the researcher to be reflexive and bracket preconceptions in accordance with the descriptive phenomenological approach although it must also be noted that that the researcher was a nurse which may have affected responses given by participants. The study used patient and public involvement to adapt and refine the interview tool, making it relevant and accessible.

Levels of anxiety and depression were not measured or graded in this study, future research in this area could help clinicians to decide on best treatment options. Additionally, future research might focus on quality of life for patients during and after pregnancy-associated thrombosis.

Conclusion

This study has shown that the experience of PRVTE is negative for women, with challenges around establishing a diagnosis, treatment with injections, anticoagulation management around the birth, fear of recurrence and implications for future pregnancies. A decade after Goldhaber [24] highlighted the tendency by HCPs to focus on the physical over psychological symptoms created by VTE, advancements are still needed in this area. HCPs can help support women through the experience with a stronger focus on the psychological effects of VTE, by providing clear information specific to pregnant and post-partum women and by ensuring effective diagnostic and treatment pathways are in place. Furthermore, there is opportunity for HCPs to increase awareness of VTE in pregnancy and post-partum since women have multiple points of contacts with HCPs from booking

through to post-natal community care. Finally, further research is needed into predictive tools for PRVTE to assist HCPs in identifying potential cases earlier.

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Disclosures of interests

The authors have no relevant conflicts to declare.

Contribution to authorship

EG was the primary researcher and drafted the manuscript. VT was the research supervisor supporting and assisting with all aspects of the study and guided and edited the manuscript. LR and RA conceived the research idea and assisted with planning and undertaking the study as well as reviewing and editing the manuscript.

Details of Ethics approval

The study was approved by the London Bridge Research Ethics Committee in April 2018 (REC No:18/LO/0284) and King's College Hospital NHS Foundation Trust Research and Innovation department.

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Table 1

Participant No.	Age at diagnosis (in years)	Ethnicity	VTE Type/ Diagnosis setting	Time VTE diagnosed in pregnancy/postpartum	Treatment	Time from VTE to interview (in months)	No. of children (at time of interview)	Other significant information
P1	30	White British	PE Inpatient	29 weeks pregnant	LMWH from diagnosis to 6 wks postpartum	11	1	History of breast cancer IVF treatment
P2	36	White British	Distal DVT Inpatient	2 weeks postpartum	LMWH for 3 months	8	1	IVF treatment
P3	24	White British	PE Outpatient	25 weeks pregnant	LMWH from diagnosis to 6 wks postpartum	21	2	
P4	39	White British	PE Inpatient	7 weeks pregnant	LMWH from diagnosis to 3 months postpartum	13	1	IVF treatment
P5	28	White British	Distal DVT Outpatient	11 days postpartum	LMWH then Rivaroxaban (not breastfeeding) total 3 months	13	1	
P6	40	White British	Distal DVT Outpatient	3 weeks postpartum	LMWH then warfarin total 3 months	18	5	
P7	34	African Caribbean	Proximal DVT Outpatient	8 weeks pregnant	LMWH (treatment dose) from diagnosis to 6 weeks postpartum	2	1	Previous DVT in pregnancy (Had thromboprophylaxis in pregnancy)

P8	36	White British	Proximal DVT Outpatient	8 weeks pregnant	LMWH from diagnosis to 6 weeks postpartum	24	1	Previous DVT (No thromboprophylaxis in pregnancy)
P9	28	African Caribbean	PE Inpatient	30 weeks pregnant	LMWH from diagnosis to 6 weeks postpartum	6	1	